

MAR 15 1996

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**SUMMARY OF
SAFETY AND EFFECTIVENESS
INFORMATION**

1. **Submitter:** Varian Oncology Systems
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 Prepared: December 22, 1995
2. **Device Name:** VARiS PortalVision™
3. **Predicate Device:** Varian Electronic Portal Imaging
 System "PortalVision™"
 510 Notification K901932B
 Cleared May 3, 1991
4. **Description:** VARiS PortalVision™ is an on-line electronic portal
 imaging system which allows for verification of the
 treatment field and shielding blocks in relation to
 anatomical landmarks in radiotherapy treatment. The
 imaging mechanism of VARiS PortalVision™ is an
 ionization chamber.

 VARiS PortalVision™ is fully integrated into Varian's
 VARiS environment. It is a subsystem of the VARiS
 Images application. The VARiS PortalVision™
 software supports image acquisition, image
 processing, and image evaluation by means of
 quantitative comparison tools.

 As a subsystem of VARiS Images, VARiS Portal
 Vision™ runs on the VARiS Images workstation.
 The VARiS Images workstation is based on an Intel
 Pentium processor based PC running Microsoft
 Windows NT or the Win 95 operating system.

5. Intended Use: To assist the therapist in verification of the treatment field and shielding blocks in relation to anatomical landmarks in radiotherapy treatment.

6. Technological Considerations: VARiS PortalVision™ is Windows based and menu driven. The predicate electronic portal imaging system is character oriented and menu driven. The predicate portal imaging device provides matched sets whereas VARiS PortalVision™ provides matched sets, batch matching and scattered plots. Both of these systems provide off-line double exposure, multiple combined images and export/import functionality.